

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**



RAW SEQUENCE LISTING ERROR REPORT

The Biotechnology Systems Branch of the Scientific and Technical Information Center (STIC) detected errors when processing the following computer readable form:

Application Serial Number: 09/613,591
Source: BATCH
Date Processed by STIC: 11/30/2000

THE ATTACHED PRINTOUT EXPLAINS DETECTED ERRORS.

PLEASE FORWARD THIS INFORMATION TO THE APPLICANT BY EITHER:

- 1) INCLUDING A COPY OF THIS PRINTOUT IN YOUR NEXT COMMUNICATION TO THE APPLICANT, WITH A NOTICE TO COMPLY or,
- 2) TELEPHONING APPLICANT AND FAXING A COPY OF THIS PRINTOUT, WITH A NOTICE TO COMPLY

FOR CRF SUBMISSION QUESTIONS, PLEASE CONTACT MARK SPENCER, 703-308-4212.

FOR SEQUENCE RULES INTERPRETATION, PLEASE CONTACT ROBERT WAX, 703-308-4216.

PATENTIN 2.1 e-mail help: patin21help@uspto.gov or phone 703-306-4119 (R. Wax)

PATENTIN 3.0 e-mail help: patin30help@uspto.gov or phone 703-306-4119 (R. Wax)

TO REDUCE ERRORED SEQUENCE LISTINGS, PLEASE USE THE CHECKER VERSION 3.0 PROGRAM, ACCESSIBLE THROUGH THE U.S. PATENT AND TRADEMARK OFFICE WEBSITE. SEE BELOW:

Checker Version 3.0

The Checker Version 3.0 application is a state-of-the-art Windows based software program employing a logical and intuitive user-interface to check whether a sequence listing is in compliance with format and content rules. Checker Version 3.0 works for sequence listings generated for the original version of 37 CFR §§1.821 – 1.825 effective October 1, 1990 (old rules) and the revised version (new rules) effective July 1, 1998 as well as World Intellectual Property Organization (WIPO) Standard ST.25.

Checker Version 3.0 replaces the previous DOS-based version of Checker, and is Y2K-compliant. Checker allows public users to check sequence listings in Computer Readable form (CRF) before submitting them to the United States Patent and Trademark Office (USPTO). Use of Checker prior to filing the sequence listing is expected to result in fewer errored sequence listings, thus saving time and money.

Checker Version 3.0 can be down loaded from the USPTO website at the following address:

<http://www.uspto.gov/web/offices/pac/checker>

Raw Sequence Listing Error Summary

ERROR DETECTED SUGGESTED CORRECTION

SERIAL NUMBER: 09/613,591

ATTN: NEW RULES CASES: PLEASE DISREGARD ENGLISH "ALPHA" HEADERS, WHICH WERE INSERTED BY PTO SOFTWARE

- 1 Wrapped Nucleics The number/text at the end of each line "wrapped" down to the next line.
This may occur if your file was retrieved in a word processor after creating it.
Please adjust your right margin to .3, as this will prevent "wrapping".
- 2 Wrapped Aminos The amino acid number/text at the end of each line "wrapped" down to the next line.
This may occur if your file was retrieved in a word processor after creating it.
Please adjust your right margin to .3, as this will prevent "wrapping".
- 3 Incorrect Line Length The rules require that a line not exceed 72 characters in length. This includes spaces.
- 4 Misaligned Amino Acid Numbering The numbering under each 5th amino acid is misaligned. This may be caused by the use of tabs between the numbering. It is recommended to delete any tabs and use spacing between the numbers.
- 5 Non-ASCII This file was not saved in ASCII (DOS) text, as required by the Sequence Rules.
Please ensure your subsequent submission is saved in ASCII text so that it can be processed.
- 6 Variable Length Sequence(s) contain n's or Xaa's which represented more than one residue.
As per the rules, each n or Xaa can only represent a single residue.
Please present the maximum number of each residue having variable length and indicate in the (ix) feature section that some may be missing.
- 7 PatentIn ver. 2.0 "bug" A "bug" in PatentIn version 2.0 has caused the <220>-<223> section to be missing from amino acid sequence(s) . Normally, PatentIn would automatically generate this section from the previously coded nucleic acid sequence. Please manually copy the relevant <220>-<223> section to the subsequent amino acid sequence. This applies primarily to the mandatory <220>-<223> sections for Artificial or Unknown sequences.
- 8 Skipped Sequences (OLD RULES) Sequence(s) missing. If intentional, please use the following format for each skipped sequence:
(2) INFORMATION FOR SEQ ID NO:X:
(i) SEQUENCE CHARACTERISTICS: (Do not insert any headings under "SEQUENCE CHARACTERISTICS")
(xi) SEQUENCE DESCRIPTION: SEQ ID NO:X:
This sequence is intentionally skipped

Please also adjust the "(iii) NUMBER OF SEQUENCES:" response to include the skipped sequence(s).
- 9 Skipped Sequences (NEW RULES) Sequence(s) missing. If intentional, please use the following format for each skipped sequence.
<210> sequence id number
<400> sequence id number
000
- 10 Use of n's or Xaa's (NEW RULES) Use of n's and/or Xaa's have been detected in the Sequence Listing.
Use of <220> to <223> is MANDATORY if n's or Xaa's are present.
In <220> to <223> section, please explain location of n or Xaa, and which residue n or Xaa represents.
- 11 Use of <213> Organism (NEW RULES) Sequence(s) are missing this mandatory field or its response.
- 12 Use of <220> Feature (NEW RULES) Sequence(s) are missing the <220> Feature and associated headings.
Use of <220> to <223> is MANDATORY if <213> ORGANISM is "Artificial" or "Unknown"
Please explain source of genetic material in <220> to <223> section.
(See "Federal Register," 6/01/98, Vol. 63, No. 104, pp. 29631-32) (Sec. 1.823 of new Rules)
- 13 PatentIn ver. 2.0 "bug" Please do not use "Copy to Disk" function of PatentIn version 2.0. This causes a corrupted file, resulting in missing mandatory numeric identifiers and responses (as indicated on raw sequence listing).
Instead, please use "File Manager" or any other means to copy file to floppy disk.

BATCH

RAW SEQUENCE LISTING
 PATENT APPLICATION: US/09/613,591

DATE: 11/30/2000
 TIME: 11:09:24

Input Set : A:\A-378CIP5 US.txt
 Output Set: N:\CRF3\11302000\I613591.raw

Does Not Comply
 Corrected Diskette Needed

3 <110> APPLICANT: BOYLE, WILLIAM
 4 LACEY, DAVID
 5 CALZONE, FRANK
 6 CHANG, MING-SHI
 7 SENALDI, GIORGIO
 9 <120> TITLE OF INVENTION: COMBINATION THERAPY FOR CONDITIONS LEADING TO BONE LOSS
 11 <130> FILE REFERENCE: A-378CIP5
 13 <140> CURRENT APPLICATION NUMBER: US 09/613,591
 14 <141> CURRENT FILING DATE: 2000-07-10
 16 <150> PRIOR APPLICATION NUMBER: US 09/457,647
 17 <151> PRIOR FILING DATE: 1999-12-09
 19 <150> PRIOR APPLICATION NUMBER: US 09/350,670
 20 <151> PRIOR FILING DATE: 1999-07-09
 22 <150> PRIOR APPLICATION NUMBER: US 08/706,945
 23 <151> PRIOR FILING DATE: 1996-09-03
 25 <150> PRIOR APPLICATION NUMBER: US 08/577,788
 26 <151> PRIOR FILING DATE: 1995-12-22
 28 <160> NUMBER OF SEQ ID NOS: 168
 30 <170> SOFTWARE: PatentIn version 3.0
 32 <210> SEQ ID NO: 1
 33 <211> LENGTH: 36
 34 <212> TYPE: DNA
 35 <213> ORGANISM: Artificial Sequence
 37 <220> FEATURE:
 38 <221> NAME/KEY: misc_feature
 39 <222> LOCATION: ()..()
 40 <223> OTHER INFORMATION: Random cDNA primer with internal NotI restriction site.
 43 <400> SEQUENCE: 1
 W--> 44 aaaggaagga aaaaagcggc cgctacannn nnnnnn 36
 47 <210> SEQ ID NO: 2
 48 <211> LENGTH: 16
 49 <212> TYPE: DNA
 50 <213> ORGANISM: Artificial Sequence
 52 <220> FEATURE:
 53 <221> NAME/KEY: misc_feature
 54 <222> LOCATION: ()..()
 55 <223> OTHER INFORMATION: ds oligonucleotide adapter
 58 <400> SEQUENCE: 2
 59 tcgacccacg cgtccg 16
 62 <210> SEQ ID NO: 3
 63 <211> LENGTH: 12
 64 <212> TYPE: DNA
 65 <213> ORGANISM: Artificial Sequence
 67 <220> FEATURE:
 68 <221> NAME/KEY: misc_feature
 69 <222> LOCATION: ()..()
 70 <223> OTHER INFORMATION: ds oligonucleotide adapter

*see item 10
 on Enr summary
 sheet*

RAW SEQUENCE LISTING DATE: 11/30/2000
 PATENT APPLICATION: US/09/613,591 TIME: 11:09:24

Input Set : A:\A-378CIP5 US.txt
 Output Set: N:\CRF3\11302000\I613591.raw

```

73 <400> SEQUENCE: 3
74 ggggtgcgcag gc                               12
77 <210> SEQ ID NO: 4
78 <211> LENGTH: 18
79 <212> TYPE: DNA
80 <213> ORGANISM: Artificial Sequence
82 <220> FEATURE:
83 <221> NAME/KEY: misc_feature
84 <222> LOCATION: ()..()
85 <223> OTHER INFORMATION: PCR primer
88 <400> SEQUENCE: 4
89 tqtaaaaacga cggccagt                         18
92 <210> SEQ ID NO: 5
93 <211> LENGTH: 18
94 <212> TYPE: DNA
95 <213> ORGANISM: Artificial Sequence
97 <220> FEATURE:
98 <221> NAME/KEY: misc_feature
99 <222> LOCATION: ()..()
100 <223> OTHER INFORMATION: PCR primer
103 <400> SEQUENCE: 5
104 caggaaacag ctatgacc                         18
107 <210> SEQ ID NO: 6
108 <211> LENGTH: 20
109 <212> TYPE: DNA
110 <213> ORGANISM: Artificial Sequence
112 <220> FEATURE:
113 <221> NAME/KEY: misc_feature
114 <222> LOCATION: ()..()
115 <223> OTHER INFORMATION: T3 primer
118 <400> SEQUENCE: 6
119 caattaaccc tcactaaagg                       20
122 <210> SEQ ID NO: 7
123 <211> LENGTH: 23
124 <212> TYPE: DNA
125 <213> ORGANISM: Rattus rattus
127 <400> SEQUENCE: 7
128 gcattatgac ccagaaaccg gac                   23
131 <210> SEQ ID NO: 8
132 <211> LENGTH: 23
133 <212> TYPE: DNA
134 <213> ORGANISM: Rattus rattus
136 <400> SEQUENCE: 8
137 aggtagcgc cttcctcaca ttc                   23
140 <210> SEQ ID NO: 9
141 <211> LENGTH: 30
142 <212> TYPE: DNA
143 <213> ORGANISM: Artificial Sequence
145 <220> FEATURE:

```

RAW SEQUENCE LISTING DATE: 11/30/2000
 PATENT APPLICATION: US/09/613,591 TIME: 11:09:24

Input Set : A:\A-378CIP5 US.txt
 Output Set: N:\CRF3\11302000\I613591.raw

```

146 <221> NAME/KEY: misc_feature
147 <222> LOCATION: ()..()
148 <223> OTHER INFORMATION: PCR primer
151 <400> SEQUENCE: 9
152 gactagtcctc acaatgaaca agtggetgtg          30
155 <210> SEQ ID NO: 10
156 <211> LENGTH: 45
157 <212> TYPE: DNA
158 <213> ORGANISM: Artificial Sequence
160 <220> FEATURE:
161 <221> NAME/KEY: misc_feature
162 <222> LOCATION: ()..()
163 <223> OTHER INFORMATION: PCR primer
166 <400> SEQUENCE: 10
167 ataagaatgc ggcgcgtaaa ctatgaaaca gcccaagtgc cttc          45
170 <210> SEQ ID NO: 11
171 <211> LENGTH: 21
172 <212> TYPE: DNA
173 <213> ORGANISM: Artificial Sequence
175 <220> FEATURE:
176 <221> NAME/KEY: misc_feature
177 <222> LOCATION: ()..()
178 <223> OTHER INFORMATION: PCR primer
181 <400> SEQUENCE: 11
182 gcctctagaa agagctggga c          21
185 <210> SEQ ID NO: 12
186 <211> LENGTH: 21
187 <212> TYPE: DNA
188 <213> ORGANISM: Artificial Sequence
190 <220> FEATURE:
191 <221> NAME/KEY: misc_feature
192 <222> LOCATION: ()..()
193 <223> OTHER INFORMATION: PCR primer
196 <400> SEQUENCE: 12
197 cgcctgtgtc catttatgag c          21
200 <210> SEQ ID NO: 13
201 <211> LENGTH: 24
202 <212> TYPE: DNA
203 <213> ORGANISM: Rattus rattus
205 <400> SEQUENCE: 13
206 atcaaaggca gggcatactt cctg          24
209 <210> SEQ ID NO: 14
210 <211> LENGTH: 24
211 <212> TYPE: DNA
212 <213> ORGANISM: Rattus rattus
214 <400> SEQUENCE: 14
215 gttgcactcc tgtttcacgg tctg          24
218 <210> SEQ ID NO: 15
219 <211> LENGTH: 24

```

RAW SEQUENCE LISTING DATE: 11/30/2000
 PATENT APPLICATION: US/09/613,591 TIME: 11:09:24

Input Set : A:\A-378CIP5 US.txt
 Output Set: N:\CRF3\11302000\I613591.raw

```

220 <212> TYPE: DNA
221 <213> ORGANISM: Rattus rattus
223 <400> SEQUENCE: 15
224 caagacacct tgaaggccct gatg 24
227 <210> SEQ ID NO: 16
228 <211> LENGTH: 24
229 <212> TYPE: DNA
230 <213> ORGANISM: Rattus rattus
232 <400> SEQUENCE: 16
233 taactttttac agaagagcat cagc 24
236 <210> SEQ ID NO: 17
237 <211> LENGTH: 33
238 <212> TYPE: DNA
239 <213> ORGANISM: Rattus rattus
241 <400> SEQUENCE: 17
242 agcgcgggccg catgaacaag tggctgtgct gcg 33
245 <210> SEQ ID NO: 18
246 <211> LENGTH: 31
247 <212> TYPE: DNA
248 <213> ORGANISM: Rattus rattus
250 <400> SEQUENCE: 18
251 agctctagag aaacagccca gtgaccattc c 31
254 <210> SEQ ID NO: 19
255 <211> LENGTH: 24
256 <212> TYPE: DNA
257 <213> ORGANISM: Rattus rattus
259 <400> SEQUENCE: 19
260 gtgaagctgt gcaagaacct gatg 24
263 <210> SEQ ID NO: 20
264 <211> LENGTH: 24
265 <212> TYPE: DNA
266 <213> ORGANISM: Rattus rattus
268 <400> SEQUENCE: 20
269 atcaaaggca gggcatactt cctg 24
272 <210> SEQ ID NO: 21
273 <211> LENGTH: 24
274 <212> TYPE: DNA
275 <213> ORGANISM: Homo sapiens
277 <400> SEQUENCE: 21
278 cagatcctga agctgctcag ttty 24
281 <210> SEQ ID NO: 22
282 <211> LENGTH: 33
283 <212> TYPE: DNA
284 <213> ORGANISM: Homo sapiens
286 <400> SEQUENCE: 22
287 agcgcgggccg cggggaccac aatgaacaag ttg 33
290 <210> SEQ ID NO: 23
291 <211> LENGTH: 33
292 <212> TYPE: DNA

```

RAW SEQUENCE LISTING DATE: 11/30/2000
 PATENT APPLICATION: US/09/613,591 TIME: 11:09:24

Input Set : A:\A-378CIP5 US.txt
 Output Set: N:\CRF3\11302000\1613591.raw

```

293 <213> ORGANISM: Homo sapiens
295 <400> SEQUENCE: 23
296 agctctagaa ttgtgaggaa acagctcaat ggc 33
299 <210> SEQ ID NO: 24
300 <211> LENGTH: 39
301 <212> TYPE: DNA
302 <213> ORGANISM: Artificial Sequence
304 <220> FEATURE:
305 <221> NAME/KEY: misc_feature
306 <222> LOCATION: ()..()
307 <223> OTHER INFORMATION: PCR primer
310 <400> SEQUENCE: 24
311 atagcggccg ctgagcccaa atcttgtgac aaaactcac 39
314 <210> SEQ ID NO: 25
315 <211> LENGTH: 45
316 <212> TYPE: DNA
317 <213> ORGANISM: Artificial Sequence
319 <220> FEATURE:
320 <221> NAME/KEY: misc_feature
321 <222> LOCATION: ()..()
322 <223> OTHER INFORMATION: PCR primer
325 <400> SEQUENCE: 25
326 tctagagtcg acttatcatt taccgagaga caggagaggg ctctt 45
329 <210> SEQ ID NO: 26
330 <211> LENGTH: 38
331 <212> TYPE: DNA
332 <213> ORGANISM: Mus musculus
334 <400> SEQUENCE: 26
335 cctctgagct caagcttccg aggaccacaa tgaacaag 38
338 <210> SEQ ID NO: 27
339 <211> LENGTH: 43
340 <212> TYPE: DNA
341 <213> ORGANISM: Mus musculus
343 <400> SEQUENCE: 27
344 cctctgagct cgctaagcag cttattttca cggattgaac ctg 43
347 <210> SEQ ID NO: 28
348 <211> LENGTH: 38
349 <212> TYPE: DNA
350 <213> ORGANISM: Mus musculus
352 <400> SEQUENCE: 28
353 cctctgagct caagcttccg aggaccacaa tgaacaag 38
356 <210> SEQ ID NO: 29
357 <211> LENGTH: 24
358 <212> TYPE: DNA
359 <213> ORGANISM: Homo sapiens
361 <400> SEQUENCE: 29
362 tccgtaagaa acagcccagt gacc 24
365 <210> SEQ ID NO: 30
366 <211> LENGTH: 31

```


VERIFICATION SUMMARY
PATENT APPLICATION: US/09/613,591

DATE: 11/30/2000
TIME: 11:09:25

Input Set : A:\A-378CIP5 US.txt
Output Set: N:\CRF3\11302000\I613591.raw

L:44 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:1